

Clinical Experience Based Data Chronicle of the Use of Mirabegron in Indian Patients with Overactive Bladder in the Real-world Setting: A Multicentre Surveillance

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ABSTRACT

Background: Overactive bladder (OAB) is a prevalent condition in both men and women and is known to negatively impact quality of life. Therefore, the present study aimed to evaluate the associated risk factors, treatment response, and safety profile of mirabegron (alone and in combination with solifenacin) in male and female patients with OAB.

Methods: A questionnaire-based study was conducted among Indian healthcare professionals (HCPs) involved in nutritional rehabilitation. The study evaluated gender distribution, OAB risk factors (like BPH, diabetes, UTI), age prevalence, causes in women, refractory cases, mirabegron treatment patterns (dose, duration, symptoms relief, compliance) and the safety, efficacy and onset of action of mirabegron alone or combined with solifenacin.

Results: A total of 41 HCPs participated in the study. About, 31.71% of HCPs reported that 4 out of 10 OAB patients were males and 78.05% of HCPs reported UTI as a contributing factor in male OAB patients. Most HCPs (58.54%) initially prescribed mirabegron 25 mg once daily and 41.46% of HCPs reported that over >80% of their patients complied to treatment. The majority (73.17%) of HCPs prescribed the mirabegron + solifenacin combination to >3 out of their last 10 patients, with 43.90% of HCPs observing symptom improvement within 2 to 3 days of starting the combination therapy. The efficacy and safety of the mirabegron-solifenacin combination rated as excellent by 58.54% and 36.59% of HCPs, respectively.

Conclusion: The questionnaire-based study indicates that mirabegron monotherapy relived symptoms in both male and female patients; however, the mirabegron-solifenacin combination was commonly used, showing improvement within 2–3 days of initiation.

Keywords: mirabegron-solifenacin combination, mirabegron, overactive bladder, quality of life, healthcare professionals.

INTRODUCTION

Overactive bladder (OAB), as described by the International Continence Society (ICS), refers to a collection of symptoms marked by

a sudden, intense need to urinate, which may occur with or without urinary incontinence. This condition is frequently accompanied by increased urination frequency and nocturia,

and is identified when no underlying infections or other medical conditions are present¹. It significantly affects the quality of life (QoL) in both men and women. Overactive bladder can occur in children and young adults; it is most frequently seen in individuals over the age of 40². Overactive bladder is a frequently occurring, persistent group of symptoms that negatively affects QoL³ and results in a notable financial burden for patients⁴. Overactive bladder interferes with daily activities and social aspects of life, including work, travel, physical exercise, sleep, and sexual health². In India, the estimated prevalence among adult men was 29.9%⁵. In 2020, the overall number of OAB cases in eight major countries—including the United States, five European nations (France, Germany, Italy, Spain, and the United Kingdom), as well as Japan and China—was estimated at around 363 million. This number is expected to grow to 401.6 million by the year 2030⁶. Current treatment approaches for OAB starts with lifestyle changes, bladder training, and pelvic floor exercises. If ineffective, medications—mainly antimuscarinics like oxybutynin, tolterodine, and solifenacin—are used⁷. Solifenacin is one of the treatment options for patients with OAB⁸. The study by Luo et al. reported that solifenacin significantly reduced episodes of urgency, incontinence, frequent urination, and nocturia, while also increasing the volume of urine voided compared to placebo⁹. Mirabegron, a novel β_3 -adrenoceptor agonist, represents the first agent in its class approved for the management OAB. Clinical evidence supports its favorable safety profile and efficacy in alleviating OAB-related symptoms². Initially approved in Japan in 2011, it received approvals in the U.S., Canada, and the EU in 2012, and later in Australia⁷. The incidence of treatment-emergent adverse events associated with mirabegron is comparable to that of antimuscarinic agents; however, mirabegron is associated with a significantly reduced risk of dry mouth and constipation³. Patients treated with a combination of solifenacin and

mirabegron experienced greater improvements in urgency, frequency, nocturia, and urge incontinence, along with fewer side effects, compared to those receiving either medication alone. This combination therapy also significantly enhanced quality of life and reduced adverse effects such as dry mouth, blurred vision, and constipation in individuals with overactive bladder¹⁰. The current study aimed to evaluate the associated risk factors, treatment response, and safety profile of mirabegron (alone and in combination with solifenacin) in male and female patients with OAB.

METHODS

Study design

This questionnaire-based study was conducted among Indian healthcare practitioners (HCPs). Participation in the study was completely voluntary, and the study process, along with the data analysis, ensured the confidentiality and anonymity of the HCPs.

Study questionnaire

The study questionnaire was designed based on existing literature, guidelines, and expert opinions. It included a total of 22 questions that focused on gender distribution, OAB risk factors (like BPH, diabetes, UTI), age prevalence, causes in women, refractory cases, mirabegron treatment patterns (dose, duration, symptoms relief, compliance) and the safety, efficacy and onset of action of mirabegron alone or combined with solifenacin. The study protocol was approved by the independent ethics committee (ACEAS-Independent Ethics Committee, Ahmedabad, Date of approval: 05 Aug 2024).

Inclusion and exclusion criteria

The study included participants involved in the management of patients diagnosed with OAB, particularly those prescribing mirabegron alone or in combination with solifenacin. These participants monitored gender specific prevalence, age distribution, associated risk factors (such as BPH, UTI,

diabetes), symptoms response, treatment duration, patient compliance, and overall, the efficacy and safety of the prescribed therapies over a treatment period of at least one month. Participants with limited experience, shorter duration of therapy and incomplete patient data were excluded.

Data collection

Healthcare practitioners participating in the study were provided with a concise overview of the study's nature and the process for completing the questionnaire. The questionnaire was given to the HCPs either in person, via phone calls, or through online platforms, as per the HCP's convenience.

Data analysis

The responses of HCPs were entered into Microsoft Excel and descriptive statistics, such as frequencies and percentages, were employed to present data.

RESULTS

A total of 41 HCPs included in this study. Among the last 10 patients, 31.71% of HCPs reported that 4 out of 10 patients with OAB were males and 31.71% of HCPs also reported that 7 out of 10 male patients with OAB had BPH (Figure 1). The majority (78.05%) of HCPs reported that UTI was a factor associated with OAB in male patients.

Additionally, 46.34% of HCPs reported that UTI was a cause of OAB, followed by advancing age (34.15%), diabetes (12.20%), recent surgery (4.88%), and neuropathic causes (2.44%). Specifically, 48.78% of HCPs reported that 10-20% of their OAB patients were under 50 years old, followed by 39.02% who reported less than 10%, and 12.20% who observed that more than 30% of their OAB patients were under 50.

The majority (58.54%) of HCPs reported that a 25 mg dose of mirabegron, taken once daily, was initially prescribed for the treatment of OAB. Among the last 10 patients treated, 39.02% of HCPs reported prescribing mirabegron for a duration of 3 months. Additionally, 41.46% of HCPs reported that >80% of their patients complied with mirabegron treatment (Table 1).

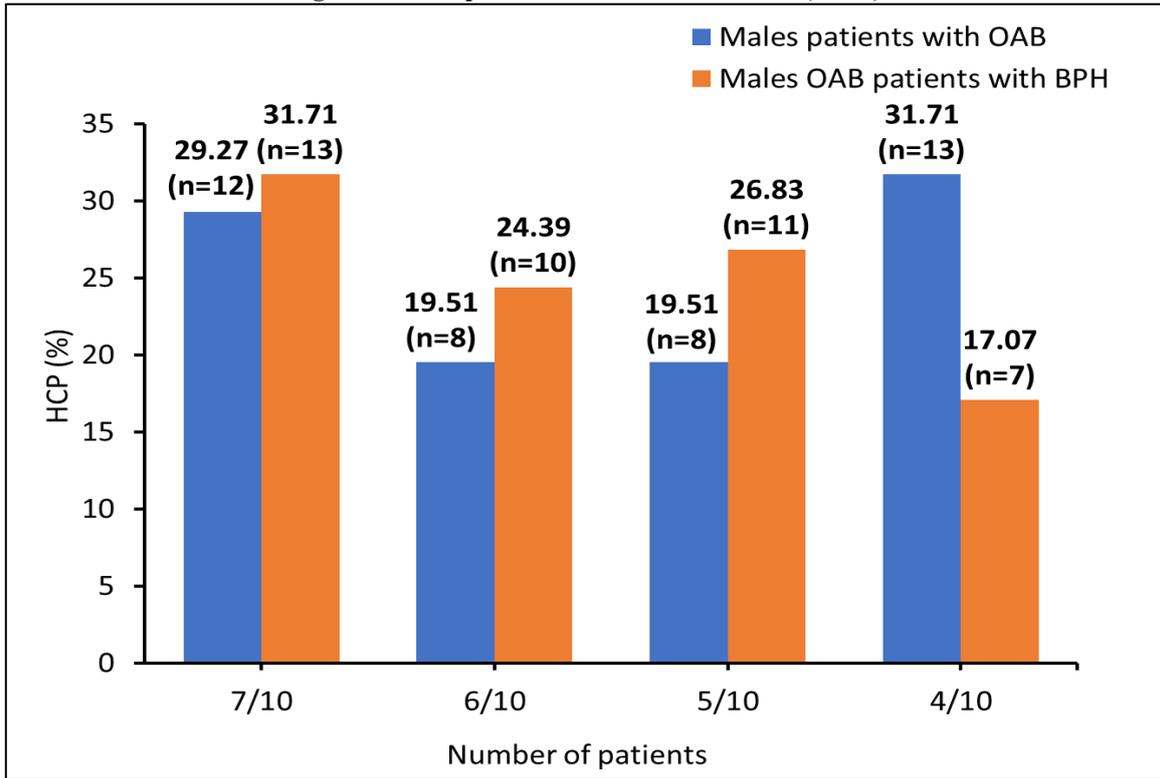
A total of 43.90% of HCPs reported that 70% of their female OAB patients treated with mirabegron experienced significant symptom relief, while 36.59% of HCPs reported the same for 70% of their male OAB patients (Figure 2). After the 1 month of mirabegron treatment, urgency symptoms, urination symptoms, nocturia episodes and incontinence episodes were reported to be moderately resolved by 43.90%, 36.59%, 53.66% and 58.54%, of HCPs, respectively (Figure 3).

Table 1: Demographics, prescription patterns, and clinical observations of mirabegron-solifenacin use in patients with OAB (N=41)

Questions	Options	Response (N=41)
What were the factors associated with OAB in male patients?	UTI	32 (78.05)
	BPH	1 (2.44)
	Neuropathic causes	2 (4.88)
	Diabetes	3 (7.32)
	Post prostate surgery	1 (2.44)
	Ureteral stent surgery	2 (4.88)
What was the cause of OAB in women?	Recent surgery	2 (4.88)
	UTI	19 (46.34)
	Diabetes	5 (12.20)
	Neuropathic causes	1 (2.44)
Do you come across OAB in patients at less than 50 years of age? If yes	Advancing age	14 (34.15)
	Less than 10%	16 (39.02)

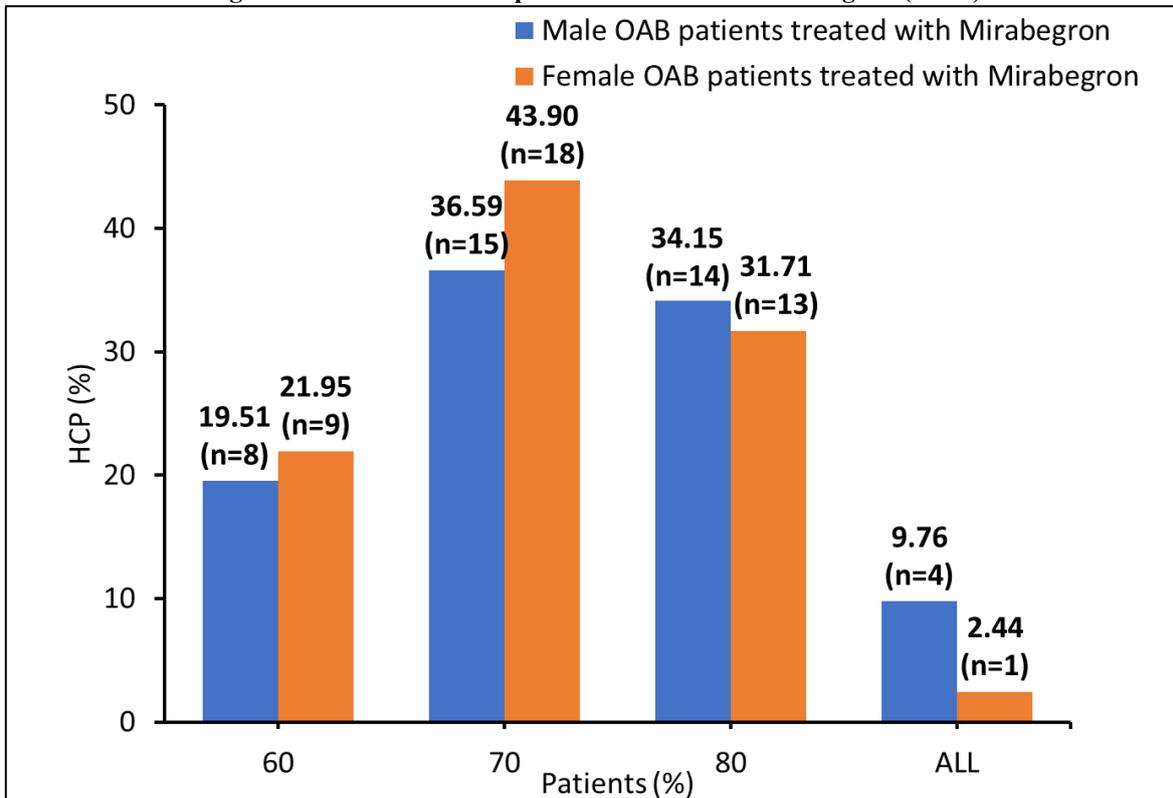
	10-20%	20 (48.78)
	Greater than 30%	5 (12.20)
What pre-existing conditions can precipitate OAB in patients <50 years of age?	URI	17 (41.46)
	Stress/Anxiety disorders	10 (24.39)
	Diabetes/Hypertension	9 (21.95)
	Thyroid issue	0.0
	Obesity	3 (7.32)
	Renal stone	2 (4.88)
How many of these 10 patients with OAB had not responded to treatment options for OAB and were considered to have refractory OAB?	1/10 patients	10 (24.39)
	2/10 patients	26 (63.41)
	3/10 patients	5 (12.20)
In women with OAB, did you give a combination of mirabegron and pelvic floor magnetic stimulation?	Yes, in some patients	22 (53.66)
	No	19 (46.34)
What dose of mirabegron did you commonly prescribe for initiating treatment?	25 mg once a day	24 (58.54)
	50 mg once a day	19 (41.46)
How long did you prescribe mirabegron treatment in these 10 patients?	1 month	13 (31.71)
	2 months	6 (14.63)
	3 months	16 (39.02)
	6 months	4 (9.76)
	>6 months	2 (4.88)
What percentage of patients comply with treatment of mirabegron?	30-50%	5 (12.20)
	50-80%	14 (34.15)
	>80%	17 (41.46)
	100%	5 (12.20)
In how many of these 10 patients, did you prescribe Mirabegron + solifenacin?	1/10 patients	1 (2.44)
	2/10 patients	10 (24.39)
	>3 patients	30 (73.17)
What was the dose of solifenacin you prescribed in these patients?	Mirabegron 25 mg + solifenacin 5 mg	22 (56.66)
	Mirabegron 50 mg + solifenacin 5 mg	19 (46.34)
In your clinical practice, how fast have you seen improvement in OAB patients after initiating Mirabegron + Solifenacin combination?	Within 24 hours	5 (12.20)
	In 2 to 3 days	18 (43.90)
	Within 5 days	11 (26.83)
	>7 days	7 (17.07)
Data presented as n (%). BPH, Benign prostatic hyperplasia; OAB, overactive bladder; UTI, urinary tract infection.		

Figure 1: Male patients with OAB with BPH (N=41)



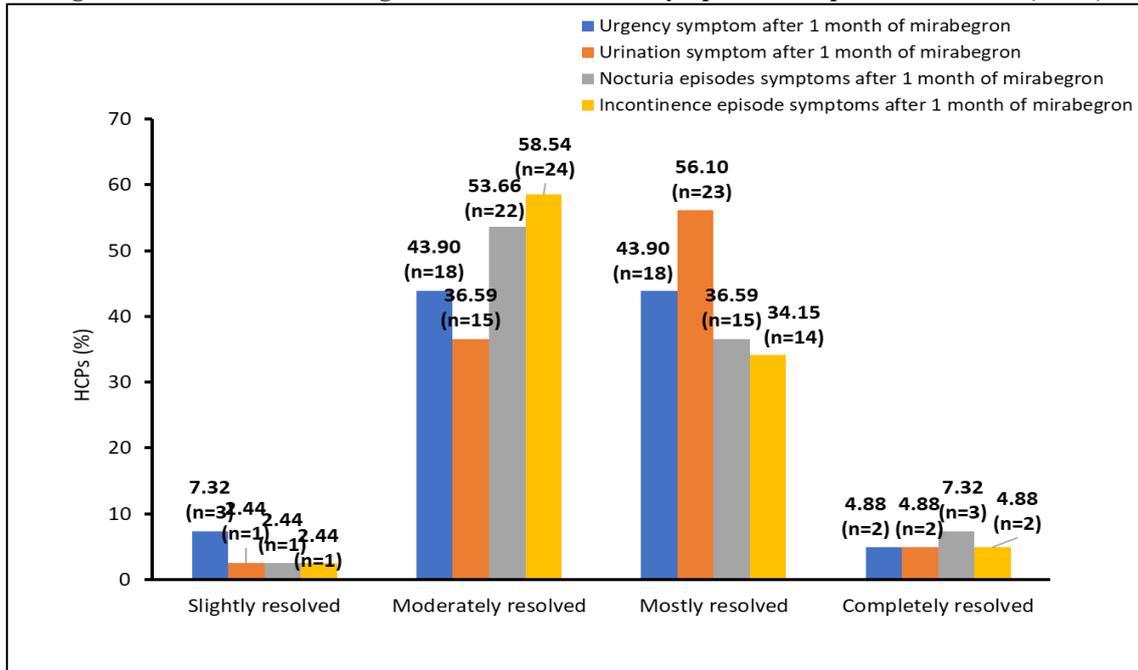
BPH, benign prostatic hyperplasia; HCPs healthcare professionals; OAB, overactive bladder.

Figure 2: Male and female patients treated with Mirabegron (N=41)



HCPs, healthcare professionals; OAB, overactive bladder.

Figure 3: One-month mirabegron outcomes in OAB: symptom and episode reduction (N=41)

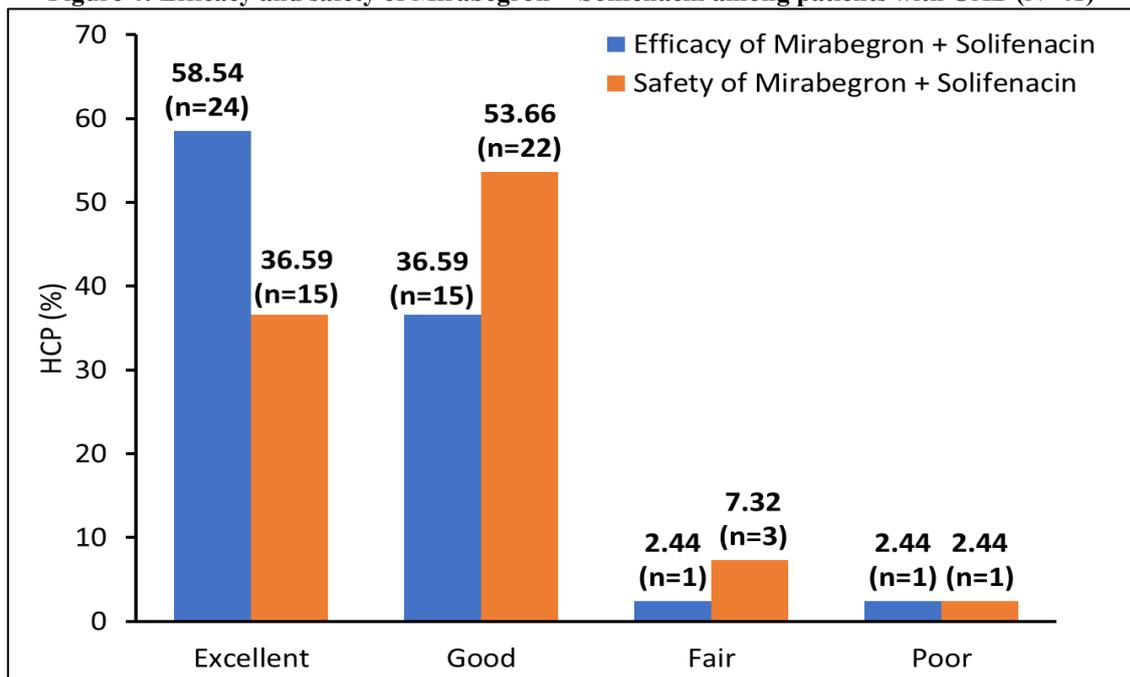


HCPs, healthcare professionals; OAB, overactive bladder.

The majority (73.17%) of HCPs reported prescribing the mirabegron + solifenacin combination to >3 out of their last 10 patients. Among the last 10 patients treated, 56.66% of HCPs prescribing the mirabegron 25 mg in combination with solifenacin 5 mg for their OAB patients. Around, 43.90% of HCPs reported that improvement in OAB

symptoms was observed within 2 to 3 days after initiating mirabegron + solifenacin combination (Table 1). The efficacy and safety of the mirabegron + solifenacin combination were reported as excellent by 58.54% and 36.59% of HCPs, respectively (Figure 4).

Figure 4: Efficacy and safety of Mirabegron + Solifenacin among patients with OAB (N=41)



DISCUSSION

Overactive bladder is a prevalent health condition, particularly among older adults, and it negatively impacts QOL. Overactive bladder is mainly treated with behavioral therapy and antimuscarinics like solifenacin, though these can cause side effects that lower QOL. Mirabegron, a newer β 3-adrenergic agonist, treats OAB by relaxing the detrusor muscle¹⁰. The current study aimed to evaluate the associated risk factors, treatment response, and safety profile of mirabegron (alone and in combination with solifenacin) in male and female patients with OAB.

In the present study 31.71% of HCPs reported that 4 out of 10 patients with OAB were males. In contrast, numerous studies have shown that OAB is more commonly observed in women than men^{11,12}. This indicates that females are more susceptible to developing symptoms associated with OAB¹⁰.

In the previous study, the average age of participants was 51.3 years. This indicates that OAB is more prevalent among individuals in the older age group¹⁰. However, in current study majority of the HCPs reported that 10-20% of their OAB patients were under 50 years of age. Mirabegron represents the first drug in a new class of agents and marks the first novel oral pharmacological treatment for OAB introduced in over three decades³. The recommended starting dose of mirabegron is 25 mg as approved by the U.S. Food and Drug Administration (FDA)⁷. In the present study, similar findings were observed, where majority of the HCPs prescribed 25 mg dose once daily. In the current study, 39.02% of HCPs reported prescribing mirabegron for a duration of 3 months. In contrast, the study by Agrawal MS et al. reported that 43.0% of HCPs typically prescribe mirabegron is for a duration of 6 to 12 months in patients with OAB. Mirabegron has demonstrated sustained clinical effectiveness and consistently high patient adherence over a treatment period of up to 12 months¹³. The study by Agrawal MS et al. reported that all participating HCPs consistently use

mirabegron as a first-line treatment, with over 75.0% of patients showing a positive response to the therapy¹³. These findings are consistent with the current study, in which more than 80% of patients adhered to mirabegron treatment. Mirabegron showed significant superiority in reducing the average volume voided per micturition, as well as the mean number of incontinence episodes, nocturia episodes, urgency incontinence episodes, and urgency episodes within a 24-hour period¹⁴. In the present study, after the 1 month of mirabegron treatment, 43.90%, 36.59%, 53.66% and 58.54%, of HCPs reported moderate improvement in urgency symptoms, urination symptoms, nocturia episodes and incontinence episodes, respectively. Similarly, the study by Agrawal MS et al. reported notable reductions in daily urinary frequency, nocturia, urgency episodes, and urgency urinary incontinence among patients receiving mirabegron monotherapy¹³.

The combination therapy of mirabegron and solifenacin demonstrated greater effectiveness and symptom relief in OAB patients compared to treatment with either solifenacin or mirabegron alone¹⁵. In the current study, the majority (73.17%) of HCPs reported prescribing the mirabegron + solifenacin combination to >3 out of their last 10 patients.

In the current study efficacy and safety of the mirabegron + solifenacin combination were reported as excellent by 58.54% and 36.59% of HCPs, respectively. In another study, efficacy findings indicate that combination therapy is more effective than either solifenacin 5 mg or mirabegron monotherapy, based on solifenacin 5 mg-adjusted and placebo-adjusted changes from baseline to the end of treatment in maximum voided volume, micturition frequency, and urgency episodes. The most effective combinations were those using 5 or 10 mg of solifenacin with either 25 or 50 mg of mirabegron¹⁶. In this study, the combination of mirabegron and solifenacin was found to be clinically effective and safe for managing OAB, as it resulted in a significant reduction

in urgency symptoms, urination symptoms, nocturia episodes and incontinence episodes. However, there are several limitations to the study. The small sample size may limit the generalizability of the findings, as the responses might not adequately reflect the larger population of HCPs. Additionally, the use of a self-reported questionnaire introduces the potential for response bias. Therefore, these limitations should be considered before drawing conclusions from the results.

CONCLUSION

This study highlights the real-world treatment patterns and clinical perspectives of HCPs managing OAB in India. Most HCPs reported that mirabegron 25 mg once daily was the most commonly prescribed initial therapy, with good treatment adherence. The questionnaire-based findings also indicate that the combination of mirabegron and solifenacin is clinically effective and safe for managing OAB in both male and female patients.

Declaration by Authors

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Conflict of Interest: All authors have no conflict of interest to declare.

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